

of food item to reduce the number of bacteria at least  $10^3$  fold in a food item for animals, and for a multi-log factor decrease in the number of non-*Lactobacillus reuteri* bacteria, and that the selection process for a bacterial strain raises an issue of new matter; (2) rejected claims 45-49 under 35 USC 112, first and second paragraphs, stating that with respect to claim 45, the antecedent basis for "said cells" is unclear and that anaerobic storage encompasses food vacuum packed, etc., and with respect to claim 47, that a culturing step seems to be missing; and that with respect to claim 46, the material intended and the control comparison are unclear, and further stating that the Casas declaration was unclear and that feeding insects and protozoa are not clearly enabled and that the papers were incorrectly cited; (3) rejected claims 45-49 under 35 USC 112, second paragraph, stating that with respect to claim 45, "significantly" is not clear; with respect to claim 47, requires selecting a strain without identifying the species; with respect to claim 48, provided recommended language of "said selected" and "as a probiotic"; and with respect to claim 49, there is a failure to further limit claim 48. These rejections are traversed in application to the claims as amended, and consideration is requested of the patentability of claim 50 now pending in the application.

(1) Rejection of claims 45-46 under 35 USC 112, first paragraph stating that there was no support in the disclosure for 200 micrograms of beta-hydroxypropionaldehyde per gram of food item to reduce the number of bacteria at least  $10^3$  fold in a food item for animals, and for a multi-log factor decrease in the number of non-*Lactobacillus reuteri* bacteria, and that the selection process for a bacterial strain raises an issue of new matter

Claims 45-46 have been canceled, and it is therefore submitted that this rejection is now moot.

(2) Rejection of claims 45-49 under 35 USC 112, first and second paragraphs, stating that with respect to claim 45, the antecedent basis for "said cells" is unclear and that

anaerobic storage encompasses food vacuum packed, etc., and with respect to claim 47, that a culturing step seems to be missing; and that with respect to claim 46, the material intended and the control comparison are unclear, and further stating that the Casas declaration was unclear and that feeding insects and protozoa are not clearly enabled and that the papers are not correctly cited

Claim 50, replacing claim 48, is the only claim now pending herein.

With respect to the papers cited in the Casas declaration, Applicant respectfully submits that these papers were not provided in an Information Disclosure Statement under MPEP 609 because all of these publications occurred substantially after the priority date of the instant application, and therefore, clearly are not "material to patentability". If the Examiner wishes Applicant to provide copies of the papers, Applicant would be pleased to do so.

Furthermore, claim 50 is now limited to birds and mammals, corresponding directly to the animals discussed in the Casas declaration and the specification herein. Thus, the specification states that the invention is feeding *L. reuteri* to animals, and discloses the production of the antibiotic, beta-hydroxypropionaldehyde at the physiological conditions that are present in warm-blooded animals, including mammals and birds. Subsequent work reported in the Casas declaration verifies the efficacy of the invention in a number of warm-blooded animal systems, as originally claimed.

Applicant therefore submits that this rejection has been overcome, and that claim 50 pending herein is patentable under section 112, first and second paragraphs.

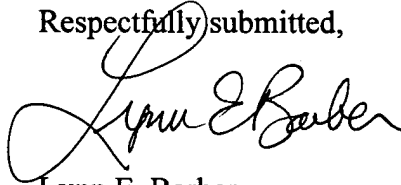
(3) Rejection of claims 45-49 under 35 USC 112, second paragraph, stating that with respect to claim 45, "significantly" is not clear; with respect to claim 47, requires selecting a strain without identifying the species; with respect to claim 48, provided recommended language of "said selected" and "as a probiotic"; and with respect to claim 49, there is a failure to further limit claim 48

Applicant has incorporated the terminology suggested by the Examiner in claim 50, which replaces claim 48 herein, and therefore submits that claim 50 is patentable under section 112, second paragraph.

For all the foregoing reasons, claim 50 is submitted to be in allowable condition. Favorable action is therefore requested. There is only one claim in this application. Any amounts that may be due for presentation of this amendment should be charged to Deposit Account No. 02-0825 of Applicant's attorney.

If any questions or issues remain, the resolution of which the Examiner feels would be advanced by a personal or telephonic conference with Applicant's attorney, the Examiner is invited to contact such attorney at the telephone number noted below.

Respectfully submitted,

A handwritten signature in cursive script, reading "Lynn E. Barber". The signature is written in dark ink and is positioned above the printed name and address.

Lynn E. Barber  
Attorney for Applicants  
Registration No. 31,734  
P.O. Box 6450  
Raleigh, NC 27628  
(919) 833-8150